CLINICAL RESEARCH PROTOCOL **INITIAL** REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name, Institute/Branch, Address, Telephone):

PROTOCOL TITLE:

ABBREVIATED TITLE (30 characters or less):

PROPOSED START DATE: _____ END DATE: _____ TOTAL SUBJECTS TO BE ACCRUED: _____

MULTI-SITE COLLABORATION:

☐ None ☐ Foreign site(s) only*
☐ Domestic site(s) only* ☐ Foreign & domestic sites*

*Include the full name and address of each site and identify whether each holds a Multiple Project or Single Project Assurance. For more information, contact the Office of Human Subjects Research (402-3444).

REQUESTED ACCRUAL EXCLUSION (Check all that apply):

☐ None ☐ Asian or Pacific Islander
☐ Male ☐ Black (Not of Hispanic origin)
☐ Female ☐ White (Not of Hispanic origin)
☐ American Indian/ Alaskan Native ☐ Hispanic
☐ Children

*Attach detailed statement describing the rationale for any requested exclusion(s).

SUBJECT ACCRUAL CHARACTERISTICS:

Median Age		☐ 0-20 Yrs.	☐ 21-65 Yrs.	☐ 66> Yrs.
Pediatric	☐ None	☐ <1 Yr.	☐ 1-3 Yrs.	☐ 4-20 Yrs.
Impaired	☐ None	☐ Physically	☐ Cognitively	☐ Both
Volunteer	☐ None	☐ Control	☐ Employee	☐ Patient
Volunteer Compensation		☐ Yes	☐ No	

NOTE: Each Protocol must include a discussion of the rationale for subject selection including gender and ethnicity of the population at risk. Recruitment plans and procedures must also be described.

SPECIAL RESOURCE REQUIREMENTS (Check all that apply)

☐ Intensive care ☐ Isolation
☐ Pediatric intensive care ☐ Gene therapy
☐ Positron Emission Tomography (PET) ☐ Controlled substance(s)
☐ Surgery ☐ Prosthetics
☐ Transfusion ☐ Gynecological services
☐ Bone marrow transplantation

KEY WORDS (Enter 5 words, not contained in the protocol title, particularly salient in describing the protocol):

1. _____
2. _____
3. _____
4. _____
5. _____

PROTOCOL TYPE:

Check one. If Clinical Trial, identify Phase.

[ ] Screening
[ ] Training
[ ] Natural History
[ ] Clinical Trial:
[ ] Phase I [ ] Phase II
[ ] Phase III [ ] Phase IV

(Definitions on Reverse)

IONIZING RADIATION USE (X-rays, radioisotopes, etc.):

☐ None
☐ Medically indicated only
☐ Research indicated (Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review.)

INVESTIGATIONAL NEW DRUG/DEVICE:

☐ None ☐ IND ☐ IDE

FDA No. _____.
Name: _____.
Sponsor: _____.
Holder: _____.

RESEARCH CONTACT (Name, Address, Telephone, FAX, e-mail):

_____.
_____.

PATIENT SELF REFERRAL ALLOWED? ☐ Yes ☐ No

LIST ON WEB (Check one) ☐ Yes ☐ No

MEDICAL ADVISORY INVESTIGATOR (If necessary):

_____.
(Name) (Institute/Branch) (Telephone)

ASSOCIATE INVESTIGATOR(S) (Name, Institute/Branch, Telephone):

1. _____.
2. _____.
3. _____.
4. _____.
5. _____.
6. _____.
7. _____.
8. _____.
9. _____.

(Principal Investigator: Be sure to include PRECIS <=400 words as first section of protocol)

SIGNATURE _____ Principal Investigator — Date _____ — Send to Accountable Investigator

RECOMMENDATION _____ Accountable Investigator — Date _____ — Send to Branch Chief, or CC Department Head of Principal Investigator

_____ Branch Chief, or CC Dept. Head of P.I. — Date _____ — Send to ICD Internal Scientific Review

APPROVALS _____ ICD Internal Scientific Review — Date _____ — Send to Clinical Director

_____ Clinical Director — Date _____ — Send to Chair, Institutional Review Board

_____ Chair, Institutional Review Board — Date _____ Protocol & Consent Approval Completed — Send to Protocol Coordination Service Center, MRD, through IRB Protocol Coordinator

_____ Director, Clinical Center — Date _____ — Return to Protocol Coordination Service Center, MRD (10/1N208)

COMPLETION _____ Protocol Specialist — Date _____ — PROTOCOL NO.